SUMMARY OF THE
QUALITY SYSTEMS COMMITTEE TELECONFERENCE
NOVEMBER 12, 1998

The Quality Systems (QS) Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met by teleconference on November 12, 1998, at 2 p.m. Eastern Standard Time (EST). The meeting was led by its chair, Mr. Joe Slayton of the U.S. Environmental Protection Agency's (EPA) Region III. A list of action items is given in Attachment A. A list of participants is given in Attachment B. A list of Parking Lot Items/Issues is included in Attachment C. A policy regarding comments is included in Attachment D. Attachment E includes the QS Committee Guiding Principles, and Attachment F is a list of Frequently Asked Questions (FAQs) Concerning NELAC QS (Chapter 5). *The purpose of the meeting was to: (a) review action items from the previous meeting, (b) review the recent draft language on calibration and detection; and (c) identify action items for the next meeting.*

REVIEW OF ACTION ITEMS FROM PREVIOUS MEETING

No changes were made to the minutes from the November 2, 1998 teleconference.

The status of homework issues dealing with review of comments received on Chapter 5 was reviewed. Also, action items from the Annapolis meeting of November 8 - 10 were reviewed.

GENERAL COMMENTS

Mr. Slayton also requested that "parking lot" issues be appended to the minutes of the meeting to remind all committee members of outstanding issues which need further discussion. The parking lot issues from this meeting are found in Attachment C.

Mr. Slayton has recommended a policy for the QS Committee for receipt and response on comments on Chapter 5. The policy is outlined in Attachment D. Various members of the committee have experienced difficulties in attempting to translate files from incompatible word processor software. It was suggested that a RTF (Rich Text Field) files in either MS Word or WordPerfect might overcome this problem. It was also requested that changes to Chapter 5 be noted using strikeout for deletions and double underline for additions.

Additional homework assignments will be made to committee members by the chair to allow review of the comments received from the Virginia NELAC Workgroup.

The issue of whether the committee should cite the International Standards Organization (ISO) Guide 25 or the newer ISO 17025 as a reference in Chapter 5 was discussed. It was agreed that since the ISO 17025 is still a draft international standard that the committee will continue to use ISO 25 until the newer document is formally adopted by ISO.

CALIBRATION AND DETECTION

The committee reviewed and discussed proposed language for Section 5.9.4. Instrument Calibrations. The committee is currently focusing on issues regarding calibration and detection.

Language proposed at the Annapolis meeting for Chapter 5 as shown in the 11/11/98 version was adopted with the following additions:

Section 5.9.4.1.c): change documentation..." to "...document..."

Section 5.9.4.2.2.f).ii: The paragraph was revised to read:

> ii. When the acceptance criteria for the continuing calibration verification check are exceeded low, i.e., low bias, ~~these~~ sample results may be reported if ~~and there are~~the associated samples ~~that~~results exceed a regulatory limit/decision level. ~~, these sample results may be reported.~~ Otherwise the samples affected by the unacceptable check shall be reanalyzed after a new calibration curve has been established, evaluated and accepted.

Section D.1.4 - Adopted as presented.

Section 5.5.3.1 Internal Audits: Revised language for this section was prepared by editing the new language submitted and from previously deleted language in the 11/11/98. The new paragraph reads:

> The laboratory shall arrange for annual internal audits to verify that its operations continue to comply with the requirements of the laboratory's quality system. It is the responsibility of the quality ~~manager~~ assurance officer to plan and organize audits as required by ~~the~~ a predetermined schedule and requested by management. Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited. Personnel shall not audit their own activities except when it can be demonstrated that an effective audit will be carried out. Where the audit findings cast doubt on the correctness or validity of the laboratory's calibrations or test results, the laboratory shall take immediate corrective action and shall immediately notify, in writing, any client whose work may have been affected.

Changes to Sections 5.1, 5.5.2, 5.5.3.2, 5.5.4, 5.6.2, 5.10.4, 5.11.3, 5.12, D.1.1, and D.1.4 were adopted as presented in the 11/11/98 version of Chapter 5.

Changes to Appendix B - Definitions for Quality Systems were discussed. The following alternate language was proposed:

> **Confirmation**: verification of the presence of a component that may include: ~~through the use of an analytical technique that differs approach different from the original test method. These may include:~~
>
> Second column confirmation
> Alternate wavelength
> Derivatization
> Mass spectral interpretation
> Alternative detectors or
> Additional cleanup procedures.
> Alternative technique or conditions

NEXT MEETING

The next meeting of the QS Committee will be a teleconference scheduled for Monday, December 7, 1998, from 2 until 4 p.m., EST. An agenda and call-in number will be distributed before the meeting.

Attachment A

ACTION ITEMS
QUALITY SYSTEMS COMMITTEE
NOVEMBER 12, 1998

Item No.	Action Item	Date to be Completed
1.	Agenda and Call-in number for next QS Committee teleconference meeting on Monday, December 7 at 2 p.m. until 4 p.m. EST	Before the 12/7/98 meeting.
2.	Mr. Slayton will assign homework to the committee to allow review and discussion of the comments received from the Virginia NELAC Workgroup	Before the 12/7/98 meeting.
3.	Ms. Mary Bruch to provide comments on "culturing" to Mr. Slayton in time for distribution for the next meeting.	Before the 12/7/98 meeting.

Attachment B

PARTICIPANTS
QUALITY SYSTEMS COMMITTEE
NOVEMBER 12, 1998

Name	Affiliation	Phone Numbers
Mr. Joe Slayton	USEPA, Region III, OASQA	T: 410-573-2653 F: 410-573-2698 E: slayton.joe@epamail.epa.gov
Ms. Mary K. Bruch	Mary Bruch Micro Reg. Inc.	T: 703- 589-1514 F: 703- 779-0267 E:
Mr. Raymond J. Frederici	Recra Labnet - Chicago	T: 708-534-5200 F: 708-534-5211 E: frederir@recra.com
Mr. Clifford R. Glowacki	Ashland Chemical Company	T: 614-790-3482 F: 614-790-4294 E: cglowacki@ashland.com
Ms. Sylvia S. Labie (Board Liaison)	Florida Department of Environmental Protection	T: 904-488-2796 F: 904-922-4614 E: labie_s@dep.state.fl.us
Mr. David Mendenhall	Utah Department of Health	T: 801-584-8470 F: 801-584-8501 E: dmendenh@doh.state.ut.us
Ms. Sheila Meyers (Absent)	Texas Natural Resource Conservation Commission	T: 512-239-0425 F: 512-239-6307 E: smeyers@tnrcc.state.tx.us
Mr. Jeff Nielson (Absent)	City of Tallahassee Water Quality Division	T: 850-891-1232 F: 850-891-1062 E: nielsenj@mail.ci.tlh.fl.us
Mr. Donivan R. Porterfield	Los Alamos National Laboratory	T: 505-667-4710 F: 505-665-5982 E: dporterfield@lani.gov
Mr. Scott D. Siders	Illinois Environmental Protection Agency	T: 217-785-5163 F: 217-524-0944 E: epa6113@epa.state.il.us
Dr. Fred Siegelman	US EPA, QAD	T: 202-564-5173 F: 202-564-2441 E: siegelman.frederic@epamail.epa.gov
Mr. Mike Beard (Contractor Support)	Research Triangle Institute	T: 202-541-6489 F: 202-541-7386 E: mebeard@rti.org

Attachment C

PARKING LOT ISSUES
QUALITY SYSTEMS COMMITTEE
NOVEMBER 12, 1998

NELAC Quality Systems Committee *Parking Lot (PL)Items/Issue* (11/12/98) :
(Items will remain in Parking Lot until completed and PL will be attached to meeting minutes)

1. Items for the NELAC Board to be forwarded by Ms. Sylvia Labie:

* Query the reason for requiring written responses for each set of comments

* Request addressing comments in chronological (first come first serve) order and QS approach:
  - = Short note acknowledging receipt and processing will be developed and routinely sent to commentors.
  - = Indicate that we prefer electronic format and specify format.
  - = Add section to routine QS meeting Agenda and associated minutes dealing with comments (which should serve as a log) and show status of whether discussed or not.

* NELAC Interim meeting and Conference Agendas: need to separate QS and On-Site so times do no overlap (at least 1/2 day without overlap). Ideally we suggest that the entire conference needs to be sequential for the standard setting committees.

*Outreach for small laboratories - what is being done? We fear they do not have the resources or time to attend committee meetings, interim meetings or the conferences. How can we help assure that they are involved with the NELAC process? *Note from the NELAP Director: ELAB established a subcommittee at the July 1998 meeting to specifically address the issues of small laboratories.*

*Should there be a breakout session at the interim to brief the whole conference on the change to 17025 - educational to present the evolution from ISO 25 - should have no vested interest in NELAC - preferably one of the authors -

*QS requests that a struck-through/underlined version of the QS chapter be available so that all other committees understand what changes are being made - ensures whether or not another committees (and all concern parties) will be aware of changes being made so they can more easily determine if the changes are of concern. In addition, this will help serve as a corporate record for the committees directly involved.

2. Air Appendix:

The Air Analysis Workgroup has a number of editorial changes which were deferred from the November 8-10, 1998 QS Committee meeting because of lack of time. These items will be discussed at that time.

3. On-Going Issues:

a) In 5.1 Scope (Section b, 2nd item): "If more stringent standards or requirements are included in a mandated test method or by regulation, the laboratory shall demonstrate that such requirements are met (See the supplemental accreditation requirements in Section 1.9.2)." What if the standards are not the same and one does not appear to be obviously "more stringent"?

[note: one thought is that perhaps this should not be a major issue given that the two standards are probably of equal merit]

In addition, changes to the standard will be proposed at the January 1999 Interim Meeting, which will no longer specify the MDL (40 CFR Part 136) procedure be employed unless it is mandated by the test method or applicable regulation.

b) MDL:

Standard needs to be searched for references to "MDL" and "3.18" (given changes being proposed for Section D.1.4 "Detection Limits"). The committee will need to decide if these are to be changed in the proposed update to the standards.

c) Revisit the Microbiology Appendix: **Need for maintaining pure cultures of bacteria.**

With regard to testing of glassware washing technique and media for laboratories that only use media and soap which comes with manufacturer's certifications.

d) Proposed New Appendix:

Appendix for listing of required records (all pulled into one table). Need to reach consensus on the table and the suggested introduction provided by D. Porterfield.

e) Continuous Monitors:

Topic was briefly discussed at the Annapolis meeting (11/10/98) and it was decided that this topic may require its own appendix with associated special QC.

f) Action Items from the NELAC IV Conference.

This was a homework item and most of the work is completed but it has not been discussed.

g) Initial Demonstration of Capability (IDOC):

Need to address an IDOC for tests for which you can not spike. Also, does IDOC need to be universal and address all medias?

h) Definitions:

Method Blank (Mr. Glowacki to provide)
Calibration Standard (Fred/Silkie to provide from QAMS reference)

i) Glossary:

Changes necessary to be consistent with Program Policy and Structure proposal.

j) Matrix and Media:

Suggestion has been made that the media definition should in turn be divided into a number of matrices. The committee has pulled into one file all items related to this issue (part of NELAC IV homework).

Attachment D

COMMENTS RECEIVED AND QS RESPONSE
QUALITY SYSTEMS COMMITTEE
NOVEMBER 12, 1998

QS Approach:

1. A form letter will be sent to each commentor notifying them of receipt of the comment and of the QS's approach to reviewing comments and associated updates to the standards.

2. QS will consider the comments in the order received.

3. A QS committee member will be designated as the lead on each set (or sub-set) of the comments from each commentor, who will provide written comments and who will lead a discussion with the full committee on any proposed changes to the standards (including providing the proposed standard language).

4. Proposed changes to the standards will be captured in the QS meeting minutes which are posted on the NELAC Web page.

5. All comments and written responses will be attached to QS meeting minutes.

6. No colors to be used in the comments nor in the response. Use double underlines for additions and strike-outs for removal of items.

7. All comments are to be provided in rich text format using the following table:

Comment ID #: , Source of Comments (Name): QS Lead on Response (Name):			
Standard Rev. # SECTION# and QS Standard Narrative (To Filled In by Commentor)	**COMMENT to QS (To Be Filled In by Commentor)**	**QS Leader Provided Proposed Change (Commentor Leave Blank)**	**RATIONAL (from QS Leader) (Commentor Leave Blank)**

LISTING OF COMMENTS YET TO BE ADDRESSED:

C20: Virginia WEA NELAC Workgroup Comments (Sept. 30, 1998)

[QS Committee will review the first 9 pages of "major concerns" as a group and will select leaders (about 3 pages for each committee member)**]**

- ISO 17025

[QS Committee will not comment as a committee, but QS members are welcome to comment as individual-indicating that their comments do not necessarily represent those of the QS committee. The QS Committee plans to schedule a meeting with invited experts on the proposed 17025 to highlight the differences between Guide 25 and the proposed standard, as well as well, to explain the vision/goals of the new standard.**]**

C21 Catalyst

[QS Committee will review comments on Matrix Spike- MSD as a group**]**

QS Committee Guiding Principles

QS Standards Should Be:

*__Flexible__ (allow laboratories freedom to use their experience and expertise in performing their work and allow for new and novel analytical and methods and approaches, e.g. Performance Based Measurement System. That the standards specify the "What" and avoid were possible the "How To", e.g., control limits must be developed to determine if a QC check result is acceptable, the standards do not specify how the laboratory is to determine these limits.

*__Auditable__ (sufficient detail is included so that the accrediting authorities evaluate laboratories consistently and uniformly).

*__Practical__ (that the standards represent essential QA policies and QC procedures and that these standards should not place an unreasonable burden upon the laboratories).

*__Internationally Applicable__ (consistent with ISO Guide 25)

Some Frequently Asked Questions (FAQs) Concerning NELAC QS (Chapter 5):

1. Question: If a mandated method (required by EPA or State Authority) is less stringent than the QS standards what do I follow?

Answer: The most restrictive/demanding.

2. Question: Do the QS standards require the use of any specific method?

Answer: No

3. Question: Do the QS standards allow for the use of the PBMS approach?

Answer: Yes. However, the QS standards may include additional QS checks/requirements (considered by NELAC to be essential) than those associated with a PBMS method for a given project. Such additional requirements would also apply to conventional or non-PBMS methods as well.

4. Question: Do the QS standards apply to small laboratories?

Answer: Yes. The standards include essential QC procedures and are applicable to environmental laboratories regardless of size and complexity. It is suggested that the amount of effort that will be required to attain the standards will be dependent on whether the laboratory already is operating under a quality system (with established and documented SOPs and QC procedures) more then upon the size of the laboratory.

5. Question: If my laboratory is measuring high level concentrations and is set-up (perhaps even optimized) to analyze at such levels and is only interested in whether a high level regulatory limit is exceeded, why do I have to determine a detection limit?

Answer: A detection limit is considered essential to verify (confirm and document) that the laboratory is actually able to detect and measure at the regulatory or decision limit. Detection limit determinations are also considered an important consideration with regards to the quantitation range selection. This is particularly true in regards to the choice of the concentration of the lowest calibration standard. Changes to the standard will be proposed at the January 1999 NELAC Interim Meeting, which no longer specify that the MDL (40 CFR Part 136) procedure be employed, unless it is mandated by the test method or applicable regulation. In the proposed revision, the term "detection limit" may not be the lowest concentration level attainable by a given analytical method, but rather that it is a concentration that is actually measurable (and verified) using the procedures, e.g., equipment, analytical method, routinely employed for sample analyses (could be relatively high concentration). The detection level should be appropriate or relevant for the intended use of the data. In some cases this will of necessity be the lowest concentration level attainable, e.g., low level drinking water or wastewater permit limits.